

## **REMARKS**

### **Status of the claims**

Claims 1, 2, 5, 6, 9, 11, 12, 18-21, 24 and 29-35 are pending in the application, with claims 34 and 35 being newly added herein. Claims 18-21 and 24 are amended herein. No new matter has been added with the amendments or new claims. As such, entry thereof is respectfully requested.

### **Rejections under 35 U.S.C. §112, 2<sup>nd</sup> paragraph**

The Examiner maintains the rejection of claims 18-21 and 24 as being unclear and indefinite for the following specific reasons.

a) Claims 18, 19 and 24 have been rejected for recitation of “DNA fragment according to claim 1.” Claims 18, 19 and 24 have been amended to delete “or DNA fragment”. Withdrawal of the rejection is respectfully requested.

b) Claim 20 has been rejected for recitation of “such as”. Claim 20 has been amended to delete the subgenus subject matter and present that subject matter as new claims 34 and 35. No new issues or new matter considerations are believed to be raised by the presentation of new claims 34 and 35. As such, entry thereof despite the fact that an equal number of claims are not concurrently being cancelled is respectfully requested.

c) Claim 21 remains rejected as being unclear in the recited method steps. Claim 21 has been amended to clarify that the steps (i), (ii) or (iii) are performed to screen for substances having the characteristics of (a)-(c). Withdrawal of the rejection is respectfully requested.

### **Rejections under 35 U.S.C. §101 and 112, 1<sup>st</sup> paragraph**

The Examiner maintains the rejection of the claims under 35 U.S.C. §§101 and §112, 1<sup>st</sup> paragraph for an asserted lack of utility. The Examiner notes that the invention must have a credible, specific and substantial utility. The Examiner notes that the asserted utility for the instant invention is credible and specific, but not substantial. With regard to the asserted lack of substantiality of the utility the Examiner states, “An assertion that the claimed polypeptides can

be used to bind the antibodies is not substantial, since it is only for further research regarding the function of the claimed polypeptides in the cell with respect to G-CSF function.”

Applicants respond, in turn, that the Examiner is legally incorrect in her position with regard to the substantiality of the utility of the invention. Section 2107.01 of the MPEP states, with regard to the requirement for a utility to be substantial that,

A "substantial utility" defines a "real world" use. Utilities that require or constitute carrying out further research to identify or reasonably confirm a "real world" context of use are not substantial utilities. For example, both a therapeutic method of treating a known or newly discovered disease and an assay method for identifying compounds that themselves have a "substantial utility" define a "real world" context of use. An assay that measures the presence of a material which has a stated correlation to a predisposition to the onset of a particular disease condition would also define a "real world" context of use in identifying potential candidates for preventive measures or further monitoring. MPEP 2701.01 (emphasis added).

The present invention has a substantial utility because the specification clearly ties the invention to the treatment, diagnosis or prevention of neutropenia. The present specification clearly describes that the gene or the protein of the present invention can be used for the treatment, diagnosis or prevention of neutropenia and anaplastic anemia (see p. 48, line 18 to page 49, line 3, of the present specification). In addition, the present specification teaches a method of screening a substance that can induce production of G-CSF, with a protein of the present invention (see Claim 21, as well as page 43, line 6 to page 45, line 21 of the specification).

Further, the protein of the present invention has the fundamental characteristic that it binds to G-CSF inducing antibody produced by the hybridoma deposited as FERM BP-6103. It was known at the filing date of the present application that the antibody produced by the hybridoma FERM BP-6103 has an ability to induce G-CSF. However, antigens recognized by the G-CSF inducing antibody had not been discovered before the filing of the instant application. As such, the mechanism by which the antibody induced G-CSF' was not known at the time of filing the present application. Under these circumstances, one skilled in the art would find it a useful and substantial utility in the identification of a protein which binds to the antibody (i.e., the protein of the present invention).

In summary, the present invention provides a new drug target for G-CSF induction. The

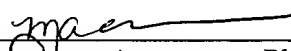
gene or protein of the present invention can be used for the treatment, diagnosis or prevention of diseases such as neutropenia and anaplastic anemia. Further, the protein of the present invention can be used in a method for screening a substance that can induce the production of G-CSF. Such a screening method is useful for obtaining novel G-CSF inducing substances (which are not limited to G-CSF inducing antibodies) that can be used as pharmaceuticals. Preliminary to establishing such screening methods is the determination of the gene and protein of invention. Thus, the gene and protein of the invention have a substantial utility. Finally, as described in the Background Art section of the specification, the fact that G-CSF exhibits a therapeutic effect on neutropenia and anaplastic anemia was known at the time of filing of the application.

Thus, the present invention has the substantial utility of treating a known disease and an assay method for identifying compounds for treating the known disease. This is a substantial utility as explicitly defined in the MPEP, and furthermore, one skilled in the art would find that the present invention has utility. Withdrawal of the rejection is respectfully requested.

In view of the above amendment, applicant believes the pending application is in condition for allowance. If the Examiner has any questions regarding the present application she is requested to please contact the undersigned.

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Respectfully submitted,

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